EXHIBIT 4

From: CBER OCOD Consumer Account
To: brookjackson04@gmail.com
Subject: 47742, FW: ATTN: Laura Re: Pfizer C4591001 Patient Safety Report
Date: Friday, September 25, 2020 12:34:18 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png

Dear Ms. Jackson:

Thank you for contacting the Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER), regarding your concerns with a Pfizer COVID-19 vaccine clinical trial. CBER, one of seven centers within the Food and Drug Administration (FDA), is responsible for the regulation of many biologically-derived products, including blood intended for transfusion, blood components and derivatives, vaccines, allergenic extracts, and cell, tissue and gene therapy products. We hope the following information will be helpful.

The information you provided was forwarded to the appropriate compliance individuals within CBER. Should there be the need for follow up on the information you provided, someone may contact you to obtain further information.

Please know that once your complaint/concerns are submitted, we are not able to comment on the progress of any investigation that may take place as a result. If an investigation is conducted, you may be able to obtain copies of the completed investigational report by submitting a Freedom of Information Act (FOIA) request to FDA. When submitting a FOIA request, please be as specific as possible with your request, specifying exactly the information that you would like to obtain. Additional information on submitting a FOIA request can be found on our website: http://www.fda.gov/RegulatoryInformation/FOI/HowtoMakeaFOIARequest/default.htm.

Please know that the Food and Drug Administration takes complaints and concerns seriously, and we thank you for bringing this to our attention.

Sincerely,

Laura Carter
Health Communications Specialist
Center for Biologics Evaluation and Research
Office of Communication, Outreach and Development
U.S. Food and Drug Administration
Tel: 800-835-4709
OCOD@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.

-----Original Message-----
From: Brook Jackson <brookjackson04@gmail.com>
Sent: Friday, September 25, 2020 10:33 AM
To: CBER OCOD Consumer Account <cberocod@fda.hhs.gov>
Subject: ATTN: Laura Re: Pfizer C4591001 Patient Safety Report

Hello Laura,

Thank you for your time this morning. It is without hesitation that I am reporting my immediate concern for subject safety in the above-mentioned trial. In total, the 3 sites have enrolled over 1,000 subjects. I am the Regional Director for 2 of those 3 sites and have been in my current position for almost 2 weeks.

I have been witness to subjects that were discharged prior to the protocol required 30 minute post dose assessment.

Subjects are dosed without PI oversight or a MD, NP or RN available in the event of a reaction.

Subjects are placed in a hallway after their injection of IP and are not being monitored by clinical staff. This is done because the practice is scheduling more subject visits than the clinic can accommodate and exam rooms are needed.

Safety assessments via e-diaries are not being completed.

SAE follow-up is not being performed in a timely manner.

Temperature excursions have not been reported, IP not quarantined and the Sponsor has not been made aware.

Protocol deviations are not being captured or reported to the Sponsor.

Laboratory specimens are mislabeled.

Site SOPs are not being followed.

Other company policies and procedure are not being followed.

HIPAA information is not being protected.

Clinical site staff are targeted for pointing out these findings.

The site is in full “clean-up” mode and bringing staff from other locations for immediate QC.

I would like to request to speak with your department regarding my concerns.

Thank you for your immediate attention.

Brook Jackson
469-505-6222